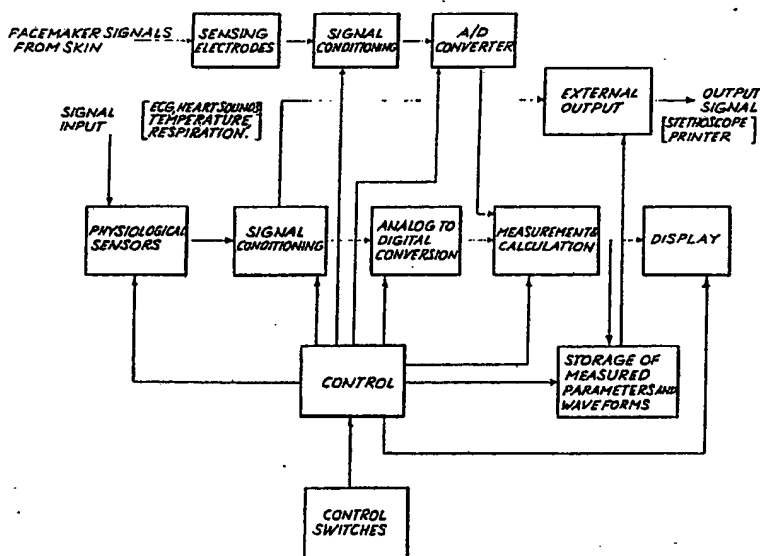


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(54) Title: COMBINED PACEMAKER PARAMETER AND VITAL SIGN MONITOR



(57) Abstract

A portable combined pacemaker parameter and vital sign monitor which acquires data relating to a patient's ECG wave form and pacemaker wave form by means of electrodes (20-23) and displays the derived wave forms on self-contained display means (31). The monitor also stores data derived from the wave forms for subsequent recall and analysis. The monitor displays wave form information in such a way that the relationship in time between the ECG wave form and the pacemaker wave form is immediately clear to a user. The monitor is particularly useful for the portable measurement of ECG and/or pacemaker wave forms and for the ongoing analysis of the condition of a working pacemaker in vivo.

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COMBINED PACEMAKER PARAMETER AND VITAL SIGN MONITORField of the Invention

The present invention relates to a hand-held instrument which combines a pacemaker monitor and an ECG monitor into a single hand-held unit.

Background of the Invention

Prior art equipment has measured pacemaker electrical pulse rate, the pulse width and in the case of dual-chamber pacemakers (which have two sources of electrical pulses) the interval between the two pulses (termed the A.V. interval). These are typically displayed as numeric information with no accompanying information concerning the patient's physiological state being measured or displayed at the same time.

The most relevant of the prior art patents/patent applications known to the applicant is Australian Patent Application AU-A 44712/85 to Purdue Research Foundation. This citation clearly discloses a portable monitor which provides ECG wave form information to a user by means of a hand held monitor which can be applied directly to the skin of the human thorax. The device of the citation, however, does not contemplate in any way the combining of ECG wave form display together with sensing and display of pacemaker wave form information.

At least a preferred embodiment of the present invention seeks to combine pacemaker parameter measurement and physiological vital signs measurement into a single portable unit. It is a further object of the preferred embodiment to display the shape of the pacing pulses which provide the doctor with further valuable information about the performance of the pacemaker and may warn of problems with the pacemaker lead which connects the pacemaker to the heart since the pacemaker pulse shape normally varies with the lead impedance.

Summary of the Invention

In accordance with one aspect of the present invention there is disclosed a portable combined pacemaker parameter and vital sign monitor: said monitor comprising data acquisition means adapted to receive electrical signals available at a skin contact region; data processing means adapted to process said data; and display means integral with said monitor; said display means adapted to display vital sign information and pacemaker parameter information.

Preferably said vital sign information includes ECG waveforms, and heart-rate.

Preferably said pacemaker parameter information includes the pacing

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rate, the AV delay, the width of the pacing pulses and the pacemaker pulse waveform.

Preferably the pacemaker signals are picked up from the skin of the patient in which the pacemaker is implanted using conductive electrodes. The signals are then amplified and filtered and converted into digital information for analysis and display.

In a further broad form there is provided a method of displaying vital sign and pacemaker pulse information on a single display means, said method comprising:

- deriving ECG wave form data from an ECG wave form occurring in a living body in real time;

- deriving pacemaker pulse data from pacemaker pulses occurring in a pacemaker operating within said living body in real time;

- displaying a reconstruction of said ECG wave form on said display means, superimposing upon said reconstruction of said ECG wave form timing markers showing the moment of occurrence of pacemaker pulses relative to said ECG wave forms.

Preferably said method includes processing said pacemaker pulse data to verify that said pacemaker pulses are stimulating the heart in a manner appropriate to the mode in which said pacemaker is operating.

Preferably said method further includes optionally displaying on said single display means a reconstruction of said pacemaker pulses.

Drawings

Two embodiments of the present invention will now be described with reference to the drawings in which:

Figure 1 is a block diagram of the monitor of a first preferred embodiment;

Figure 2 shows two display formats available from the monitor of the first and second embodiments;

Figure 3 shows a block diagram arrangement of a second embodiment of the invention;

Figure 4 shows an exploded view of the casing for the second embodiment;

Figure 5 shows details of the front cover of Figure 4;

Figure 6 shows details of the front panel from Figure 4;

Figure 7 shows details of the display window from Figure 4;

Figure 8 shows details of the back panel and electrodes (exploded view) of Figure 4;

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Figure 9 shows views of the back panel of Figure 4 in assembled form;

Figure 10 shows the mechanical arrangement of the LCD display of

Figure 4;

Figure 11 shows details of the electrodes applied to the back panel of Figure 4;

Figure 12 is a block diagram of the functional components comprising the analog block of Figure 3;

Figure 13 shows a functional block diagram of the digital block of Figure 3;

Figure 14 shows in more detail the components comprising Figure 3 and their interconnection;

Figure 15 is a flow chart of the mode switch interrupt service routine of the second embodiment;

Figure 16 is a flow chart of the main routine for ECG and heart rate display of the second embodiment;

Figure 17 is the timer interrupt service routine for the ECG and heart rate display of the second embodiment;

Figure 18 is the flow chart of the QRS detection algorithm for the ECG and heart rate display of the second embodiment;

Figure 19 is the flow chart of the main routine for the pacemaker pulse display algorithm of the second embodiment; and

Figure 20 is a flow chart of the pulse interrupt service routine for the pacemaker pulse display of the second embodiment.

Detailed Description of the Invention of the Preferred Embodiments

The first and second embodiments of the present invention have, as a common aim, the production of a portable, hand held monitor which allows the in situ monitoring of both the ECG wave forms of a patient and the wave forms produced by a pacemaker module which is installed and operational in the patient's body. The monitor of the preferred embodiments carries out these two complementary functions in a non-invasive manner and in real time.

Furthermore, a predetermined amount of data derived by the monitor is

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stored within the monitor for subsequent analysis or transmission to remote data processing means thereby enhancing the utility of the portable monitor.

First Embodiment

The device of the first embodiment combines all of the features disclosed in the device of copending PCT Application No. AU88/00016 (ie the obtaining and display of ECG information, heart sounds, temperature and respiration by means of a hand held, portable device which incorporates multi-functional electrodes) together with the deriving and display of pacemaker pulse information on the same display, the pacemaker pulse information being derived from the same multi-functional electrodes. Information for display is derived generally as shown in the block diagram of Figure 1. The display essentially takes one of two available formats at any one time: the two formats are shown in Figure 2. It will be noted that the screen output labelled as display 1 in Figure 2 shows a derived QRS wave form 3 having superimposed thereon vertical bars or timing markers 4, these bars or timing markers showing the relative position of the pacemaker pulses 5 and 6 in time relative to the QRS wave form.

Atrial, ventricular and dual-chamber pacemakers are all able to be monitored, with accurate measurements of the pacemaker parameters clearly displayed.

The ECG is also displayed on the clear, high resolution screen to observe cardiac and pacemaker function, and ensure that reliable heart capture is occurring.

The pacing pulse waveforms are also able to be displayed, allowing observation of pulse shape to highlight any anomalies or gross changes in lead pacing impedance.

Hard copy recordings of the pacemaker parameters, ECG, and pacing pulse waveforms can be made on an optional paper strip recorder.

The preferred embodiment not only displays physiological signals but also displays measurements and waveforms relating to implanted pacemaker electrical activity. This is performed by monitoring electrical pulses on the skin which originate from the implanted pacemaker.

The first preferred embodiment of the present invention is encased in similar fashion to the portable physiological monitor disclosed in Australian Specification PH 09984 which has been subsequently published under PCT Application No. AU88/00016, the text and drawings of which are incorporated herein by cross reference.

Essentially electrical signals are derived from the skin of a patient by means of a three electrode structure or equivalent. Referring to Figure

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1 the signals from the sensing electrodes are fed to a signal conditioning unit thence converted to digital form and subsequently processed by the device according to the general block diagram of Figure 1. The processed information is displayed as generally shown in Figure 2.

Referring to Figure 2, information displayed on the output display is as follows:

ECG

A waveform display of the heart's electrical activity (electrocardiogram) 3 is shown with vertical bars 4 being added to show the position of the pacemaker pulses 5 and 6 in relation to the ECG 3.

PACEMAKER PULSE WAVEFORM

The actual shape of the pacemaker pulses 5 and 6 are displayed to highlight any abnormalities which may be due to a fault in the pacemaker or pacemaker lead.

HEART RATE

Numeric information 6 showing the patient's heart rate is displayed on the screen 1 at the same time.

PACING RATE

The rate at which the pacemaker is emitting pulses to the heart is displayed as numeric information.

AV DELAY

In the case of a "dual-chamber" pacemaker which has two sources of pacing pulses, the delay between the pulse from one source to the pulse from the other is known as the A.V. Delay and is displayed as numeric information 7.

PULSE WIDTHS

The width 8, 9 of the pacing pulses is displayed numerically, typically in the range 0.25 to 1 millisecond. The atrial pacing pulse width 8 is displayed separately from the ventricular pacing pulse width 9.

An example of two typical displays is shown in Figure 2. The user can switch between the two displays by means of a mode control button (not shown) on the device.

Specifically in Figure 2, display 1, a heart rate of 70 beats per minute is shown 6 and an AV interval of 160 ms is shown 7. In display 2 of Figure 2 an atrial pacing pulse width of 0.50 ms is shown 8 and a ventricular pacing pulse width of 0.75 ms 9 is shown.

Second Embodiment

The device of the second embodiment is constructed functionally according to the block diagram of Figure 3. Four electrodes 20, 21, 22, 23

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receive low level signals from a patient. The signals are initially processed by an "analog block", which block separates out signals associated with the ECG wave form of the patient and also (and separately) those signals associated with a cardiac pacemaker operational within the patient's body. The analog block 24 then feeds the pacemaker pulse signal 64 and the ECG signal 63 (by way of analog to digital converter 25) to a digital processing block 26. The digital processing block processes the pacemaker pulse signal and the ECG signal and displays appropriate process information on the front panel display 27 in conjunction with the operators requirements as expressed by appropriate operation of the side mounted switches (block 28 of Figure 3).

Figures 4 to 10 show arrangements of the casing of the second preferred embodiment. With particular reference to Figure 4 the exploded view shows the casing to comprise a front cover 29 and a back cover 30 between which are sandwiched a liquid crystal display panel 31, a back light panel 32 and a printed circuit board 33. A display window cover 34 is applied to the front face of the front cover 29. The liquid crystal display 31 is viewed through this display window 34. The electrodes 20, 21, 22 and 23 (23 not shown) are affixed to the back cover 30 and provide the principal means of deriving ECG and pacemaker signal information from the patient when the monitor is used in portable mode. Information can also be input to the device through the patient cable connection 41. Primary controls for operating the monitor comprises on/off switch 39, "hold" push button 36, "record" push button 37 and "mode" toggle push button 38. A battery cover 35 covers the batteries once they are placed within the casing. An infrared link 42 is used to communicate data derived by the monitor to other data processing means.

The front cover is mated with the back cover in permanent fashion by use of socket screws being the same screws which hold the electrodes 21-23 to the back cover.

The LCD display used incorporates trapezoidal picture elements with a denser layout. The display sweep speed is 12.5 mm per second, the viewing area is 38.1 by 50.8 mm. The trapezoidal picture elements are arranged in a 120 x 480 matrix thereby comprising a total of 57,600 elements. The element itself is a TN type liquid crystal.

The electrodes 20-23 each comprise a section from a 16 mm diameter stainless steel (AISI type 316 stainless steel) rod. The working thickness of the electrodes is 3 mm.

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The electronics of the device are primarily incorporated on the one printed circuit board 33. The board incorporates the analog block 24, the analog to digital converter 25, the digital block 26 and an electronic power supply 54.

The analog block 24 is shown in greater functional detail in Figure 12. Functionally Figure 2 operates as follows:

The signal from the skin electrodes 20-23 is amplified by a factor of 10 in the instrumentation amplifier 40. It is then filtered through an 0.5 Hz high pass filter 41 to reduce base line movement on the output screen. Then the signal is split and fed to the ECG channel 45 and the pacemaker-pulse channel 52.

The first signal is amplified by 100 and filtered with a low pass filter (LPF) of 100 Hz. This output is taken to the A/D converter (integral within CPU 57) and used as the ECG signal 63.

The second channel signal; the pacemaker pulse signal, is divided by 4 from the output of the high pass filter (HPF) 41. A digitally gain-controlled amplifier 48 is subsequently used to amplify the pulses for signal processing. It is controlled by the CPU 57 (refer digital block description). The output of the amplifier provides an input to the second channel of the A/D converter 52 and is later displayed on the LCD screen 31. A HPF 49 of 4 KHz is used to remove low frequency skin vibrations and detect pulse edges. A constant threshold is used to differentiate between noise and pulses. A comparator 50 compares the threshold level with the pulse edges and produces a start and end of pulse timing signal. These allow the CPU to calculate the duration of the pulse. An interrupt is generated 3 ms after the beginning of pulse to start the pulse processing routine in the CPU 57.

The other major functional component on the printed circuit board 33 is the digital block 56. Functionally this block is generally as shown in Figure 13. Note that the analog to digital converter 25 (refer to Figure 3) is, in fact, on board the microprocessor (CPU 57) on the digital block 56.

Figure 14 shows in greater detail the components of the main printed circuit block 33 and their interconnection.

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The software for execution by the CPU 57 is shown in flow chart form in Figures 15 through to 20 inclusive.

An on-chip A/D converter and timer are used for sampling ECG channel 63 and pacemaker channel 64. The input capture registers IC1, IC2 and IC3 (internal to processor) are used for detecting pacemaker spikes. In response to a detected pacemaker spike, the monitor hardware generates two pulses at the IC1 and IC2 inputs to mark the start and end points of the pacemaker spike. Timing information with regard to these events is then automatically stored in IC1 and IC2 input capture registers. A 3 ms delayed interrupt pulse following the end of pacemaker spike is applied to IC3 input. This pulse sets the necessary interrupt for the service routine which then stops sampling and calculates the pulse width as the time difference between IC1 and IC2 register contents. The 3 ms delay ensures that the complete shape of the pacemaker pulse is sampled and stored in the buffer.

When the power is first turned on (by switch 39), the program starts with the main ECG and heart rate display routine as shown in the software flow charts. The mode switch 38 is assigned to the highest priority interrupt and when pressed toggles between ECG and pacemaker pulse modes. The ECG routine consists of a main routine for displaying graphics and an interrupt service routine for sampling, filtering and QRS wave form detection. The following routines are shown in the flow charts:

- main routine
- interrupt service routine
- QRS detection algorithm.

Similarly, the pacemaker pulse display consists of a main routine for continuous sampling the pacemaker channel and an interrupt service routine to stop sampling and display pulse information and shape. These routines are also shown in the flow charts.

The performance characteristics of the monitor of the second

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embodiment are as follows:

ELECTRICAL CHARACTERISTICSECG Circuit

Frequency Response:	0.5 - 100 Hz (-3dB max)
CMMR:	u 80 dB 0-100 Hz
Isolation:	Infrared external output
Pacemaker Artifact:	Pulse re-insertion

Display

Sweep Speed:	12.5 mm/sec (for ECG)
Viewing Area:	38.1 x 50.8 mm
No. of Pixels:	57,600 (120 x 480)
Display Element:	TN type LCD
Element Shape:	Trapezoidal
Back Light:	Electroluminescent

Measured Parameters

Heart Rate (HR):	0-255 bpm (+ 1 bpm)
Pacemaker Rate (PR):	0-255 bpm (+ 1 bpm)
A-V Delay Interval (AVI):	1-300 ms (+ 1 ms)
Atrial Pulse Width (APW):	0.1-2.5 ms (+ 5 ms)
Ventricular Pulse Width (VPW):	0.1-2.5 ms (+ 5 ms)

Displayed Parameters

Atrial Pulse Wave Form:	Accuracy of +5 ms
Ventricular Pulse Wave Form:	Accuracy of + 5 ms
Calibration:	1mV/cm square wave
ECG wave form:	Sweep speed 12.5 mm/sec

Power Requirements

Battery Type:	2 x AA Alkaline cells
Battery Life:	u 4 hours continuous use

Physical Characteristics

Length:	13.4 cm
Width:	8.5 cm
Thickness:	2.6 cm
Weight:	410 gm

Environmental Characteristics

5.3.1 Temperature

Operating:	5° to 45°C
Storage:	-15° to 55°C

5.3.2 Humidity

Operating:	10% to 95%
Storage:	10% to 80%

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The functional behaviour of the monitor of the second embodiment with reference to the controls and display previously described are as follows:

OPERATOR CONTROLS

On/Off

When switch 39 is switched to the ON position the ECG monitor mode is invoked. In the OFF position all operation modes are powered down, with the exception of the data in memory which is retained until the system is reset manually or by output to a printer or computer.

Contrast

A potentiometer 40 is used to control the contrast level to the LCD 31.

Hold

A momentary push button 36 that causes the current display to be frozen. No data update occurs at this time.

Record

A momentary push button 37 that initiates the recording of the current displayed data for a 10 second interval. There are six intervals available for recording. At the commencement of the recording a 1 mV calibration signal is displayed.

Mode

A momentary push button 38 that toggles between the ECG/heart rate display and the pacemaker wave forms and data display. (Refer Figure 2.)

Reset

By depressing MODE 38 and RECORD 37 buttons simultaneously the recording memory is reset, clearing all previously recorded data.

INDICATORS

Heart Rate (HR)

The heart rate is indicated on the LCD 6 (display 1 of Figure 2) and determined by using a four beat running average of the R to R interval.

Pacemaker Rate (PR)

The pacemaker rate is indicated separately on the LCD 31 and represents the actual pacing rate. Should there not be "capture" the paced rate as well as the heart rate will be displayed.

Atrio-Ventricular Delay Interval (AVI)

The A-V delay is measured in milliseconds and displayed 7 on the pacemaker data screen.

Atrial Pulse Width (APW)

The atrial pulse width is measured and displayed 8 when an atrial pulse is present. In addition the atrial wave form 5 is displayed.

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Ventricular Pulse Width (VPW)

The ventricular pulse width is measured and displayed 9 when a ventricular pulse is present. In addition the ventricular waveform is displayed 10.

Low Battery

Should the operational voltage drop below an optimal level a continuous audible tone is sounded for 1 second. At this time the procedure should be completed as soon as possible and batteries replaced or re-charged.

Functional Test

The monitor becomes operational in the ECG monitor mode when the power switch is turned ON. At this time a test cycle of 1 second is initiated to check the microprocessor function, memory integrity, and display characteristics, with a separate battery voltage check. On completion of the test cycle a 1 second audible tone is sounded to indicate correct functional operation.

Calibrate

At the RECORD button being depressed a 1 mV calibration pulse is inserted initially to allow accurate wave form analysis.

INPUT/OUTPUT CONNECTORSPatient Cable Input

The patient cable input is a Lemo Series "OB" fixed socket connector. It has three inputs RA, LA and RL to obtain the ECG/pacemaker signals.

Infrared Output Link

The infrared output 42 is a bi-directional communications link. This output provides total electrical isolation when connected to external devices, such as printers, computers or serial communications links.

In summary, the monitor of the second embodiment behaves as previously described within the following limits:

Pacemaker parameters are measured by detecting the pacing pulse artifacts on the skin surface, then amplifying and filtering them and converting them to digital signals for analysis by the CPU 57 of the second embodiment.

The digital hardware and software is capable of resolving pacing pulse widths down to 1 μ s with a resolution of $\pm 0.5 \mu$ s. The AV delay and pacing rate can be resolved to $\pm 128 \mu$ s, though with software changes this can be reduced to $\pm 0.5 \mu$ s.

The actual resolution of the pacing pulse widths is governed by the

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analog circuitry. Two factors are important here. Slew rate limitations of the amplifiers mean that there may be an error of 1 us. The second factor is really one of the definition of pacing pulse width. Pacemaker manufacturers may define the pulse width at a different level on the pulse compared with the monitor of the second embodiment and may also measure them in vitro. Depending on the characteristics of the pulse, this may amount to an error of up to 5 us when compared with the published specification of the pacemaker.

Taking all these factors into account, the monitor of the second embodiment can satisfactorily measure pacing pulse widths down to 10 us if required with a resolution of ± 1 us, though measurement may vary in some cases by up to 5 us from pacemaker published data due to a difference in measurement technique between the monitor and the pacemaker manufacturer. AV delays and pacing rates have a resolution of ± 128 us.

Importantly too the onboard memory storage of the device combined with the option to actually store data derived by the monitor within the monitor casing allows a medical practitioner to take the monitor of either the first or the second embodiment into the field and take "samples" of a patient's ECG and pacemaker wave form behaviour for subsequent analysis in the office. Similarly, a patient can be supplied with a monitor and instructed to take samples of the patient's own wave forms him or herself at predetermined times each day or during or following specific "events". The whole monitor can then be given to the practitioner at a later time at which time the practitioner can recall the stored data and analysis it.

The above describes only two embodiments of the present invention and modifications, obvious to those skilled in the art, can be made thereto without departing from the scope and spirit of the present invention.

For example, the infrared link 42 can be replaced by a RF radio link or an ultrasonic communications link. In all cases the purpose of the link is to provide a wire free means of communicating data derived by the monitor of the invention to remote data processing and/or recording means and/or hard copy means to allow subsequent and/or concurrent display and analysis of a patient's ECG and pacemaker wave forms and, most importantly, the interaction between those two wave forms.

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COMBINED PACEMAKER PARAMETER AND VITAL SIGN MONITOR

1. A portable combined pacemaker parameter and vital sign monitor, said monitor comprising:

data acquisition means adapted to receive electrical signals available at a skin contact region;

data processing means adapted to process said data; and

display means integral with said monitor;

said display means adapted to display vital sign information and pacemaker parameter information.

2. The monitor of Claim 1 wherein said vital sign information includes ECG wave forms and heart rate.

3. The monitor of Claim 2 wherein said pacemaker parameter information includes pacing rate, AV delay, width of pacing pulses and the pacemaker pulse wave form.

4. The monitor of Claim 3 wherein said pacemaker signals are picked up from the skin of a patient in which said pacemaker is implanted by means of conductive electrodes.

5. The monitor of Claim 1 incorporating memory means to retain said data and vital sign information and pacemaker parameter information derived from the processing of said data by said monitor.

6. The monitor of Claim 1 further including means to transmit said data and/or said vital sign information and said pacemaker parameter information derived by processing said data to remote data processing means.

7. The monitor of Claim 6 wherein said means for transmission comprises either an infrared link or a radio frequency link or an ultrasonic link.

8. A method of displaying vital sign and pacemaker pulse information on a single display means, said method comprising:

deriving ECG wave form data from an ECG wave form occurring in a living body in real time;

deriving pacemaker pulse data from pacemaker pulses occurring in a pacemaker operating within said living body in real time;

displaying a reconstruction of said ECG wave form on said display means, superimposing upon said reconstruction of said ECG wave form timing markers showing the moment of occurrence of pacemaker pulses relative to said ECG wave form.

9. The method of Claim 8 wherein said method includes processing said pacemaker pulse data and ECG wave form data to verify that said

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pacemaker pulses are stimulating the heart in a manner appropriate to the mode in which said pacemaker is operating.

10. The method of Claim 8, said method further including optionally displaying on said single display means a reconstruction of said pacemaker pulses.

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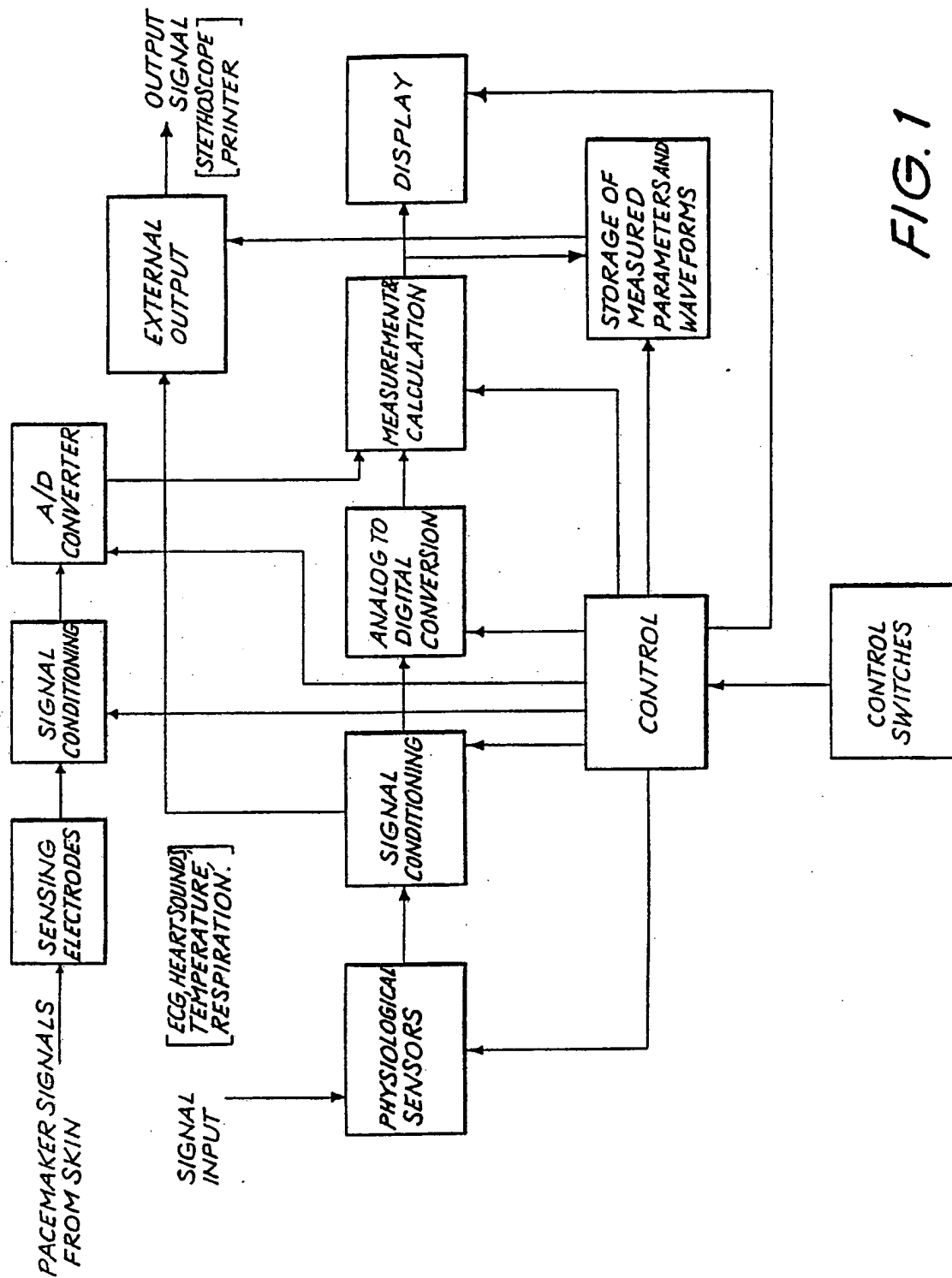
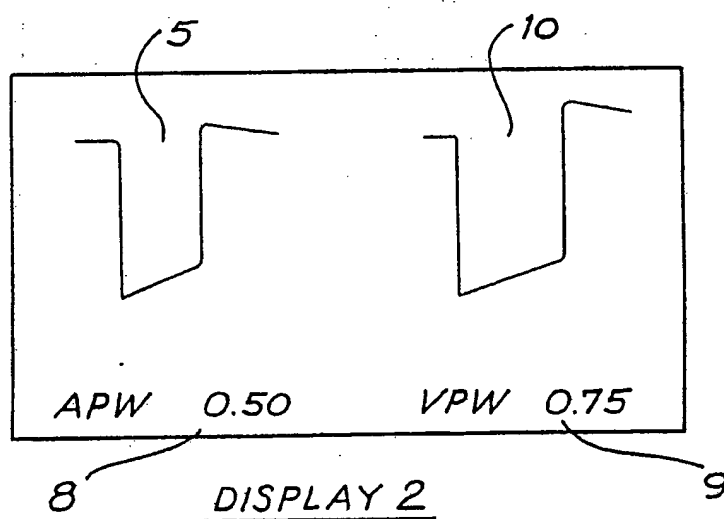
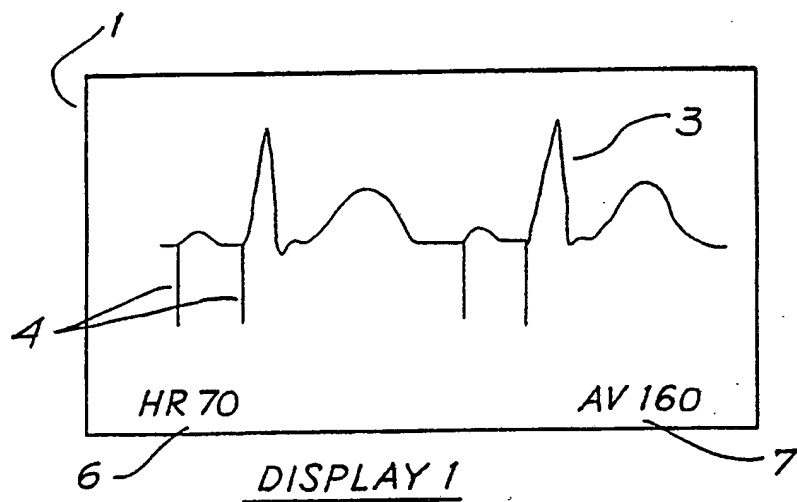


FIG. 1

FIG. 2



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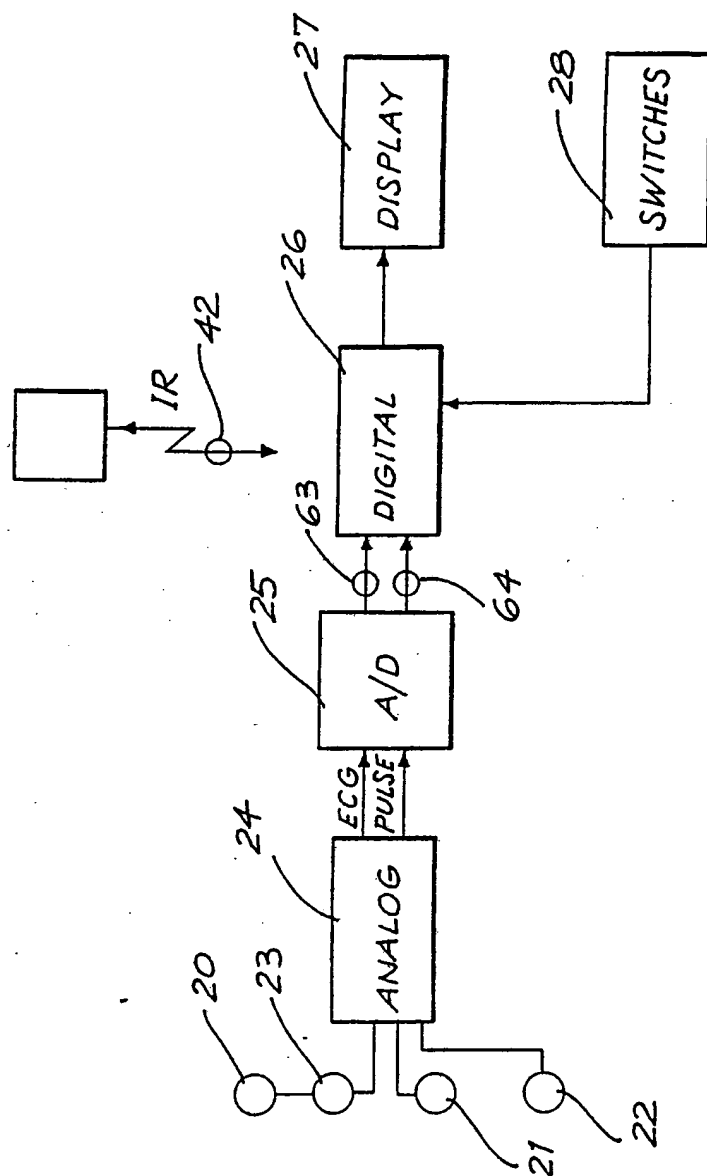


FIG. 3

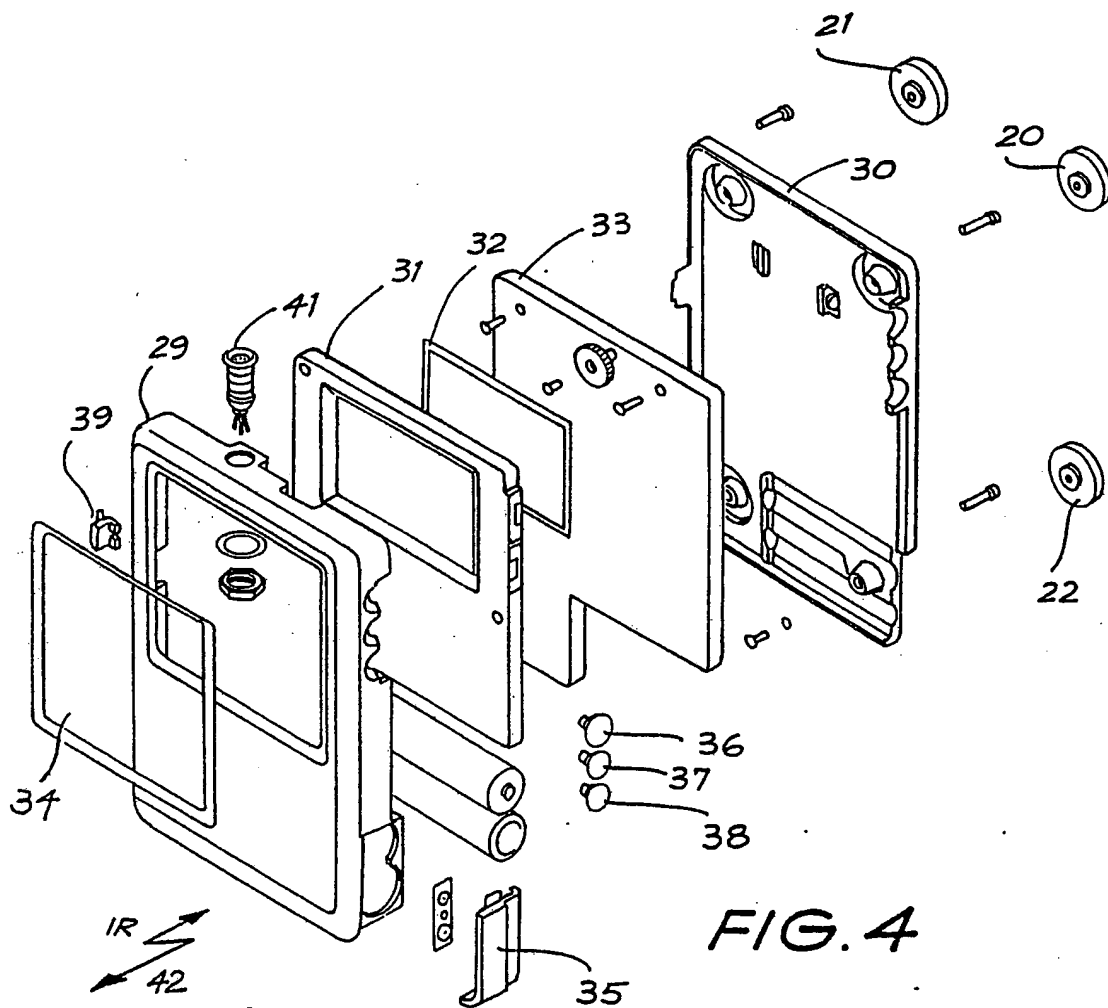


FIG. 4

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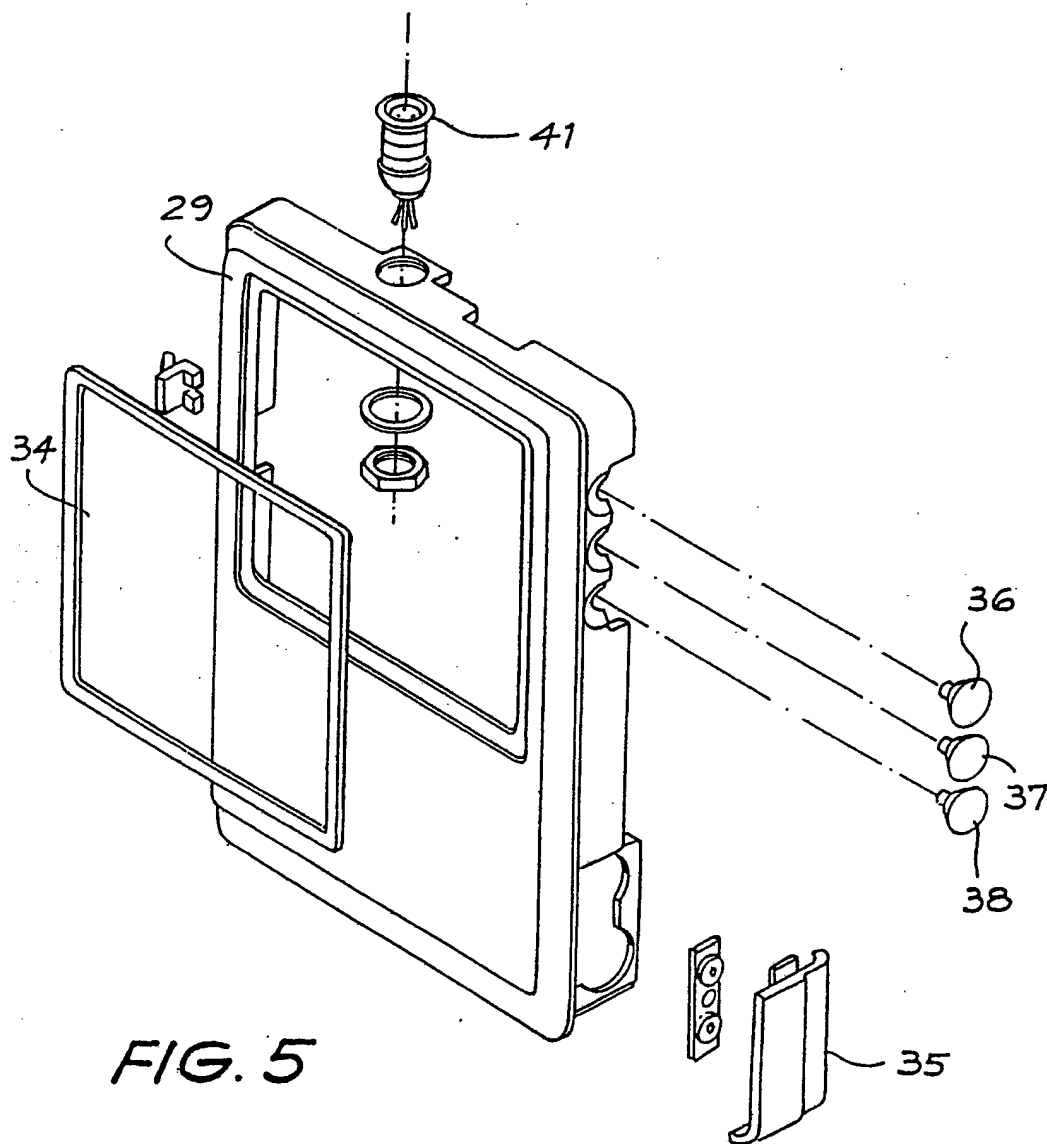
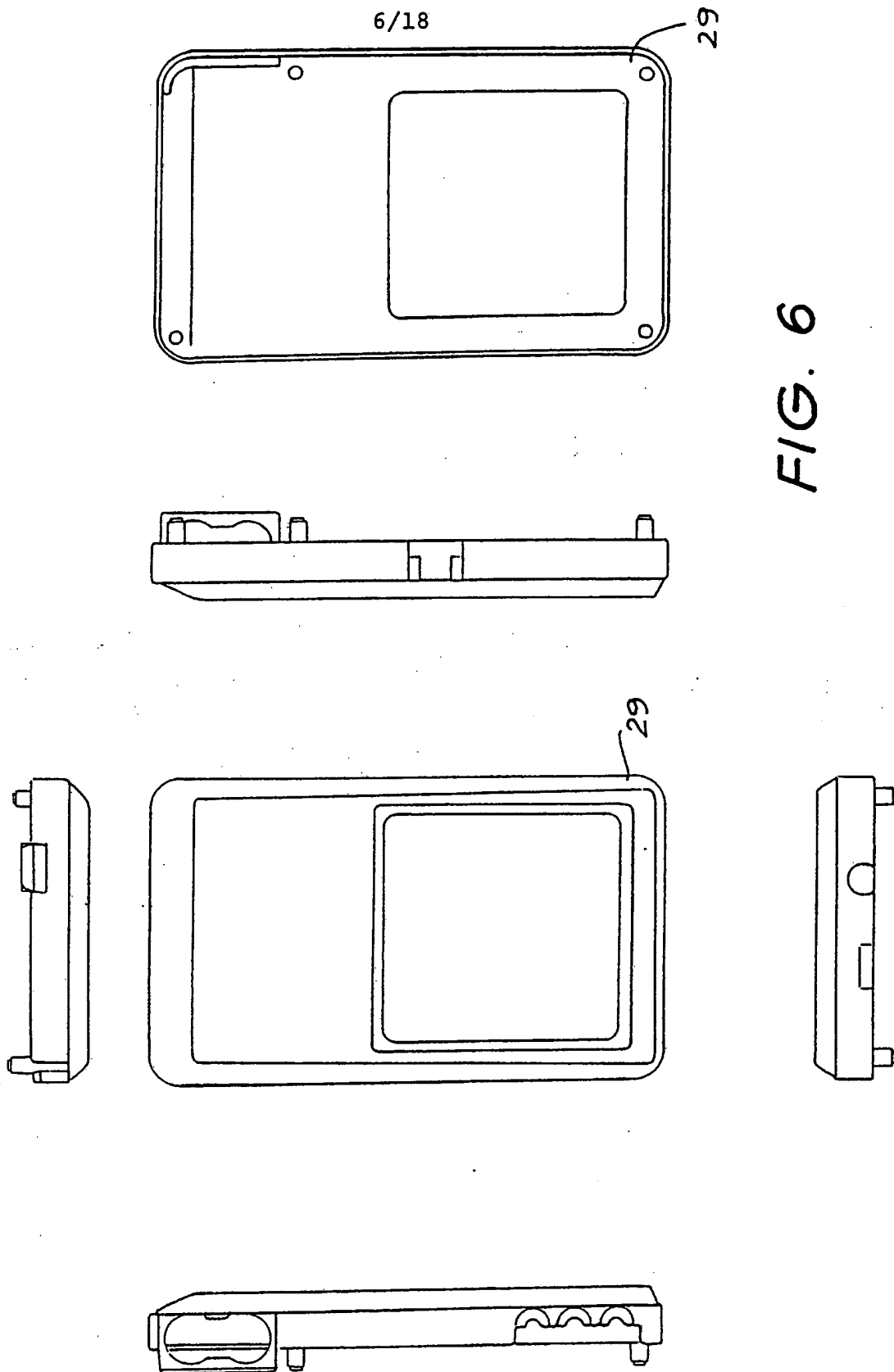


FIG. 5

SUBSTITUTE SHEET



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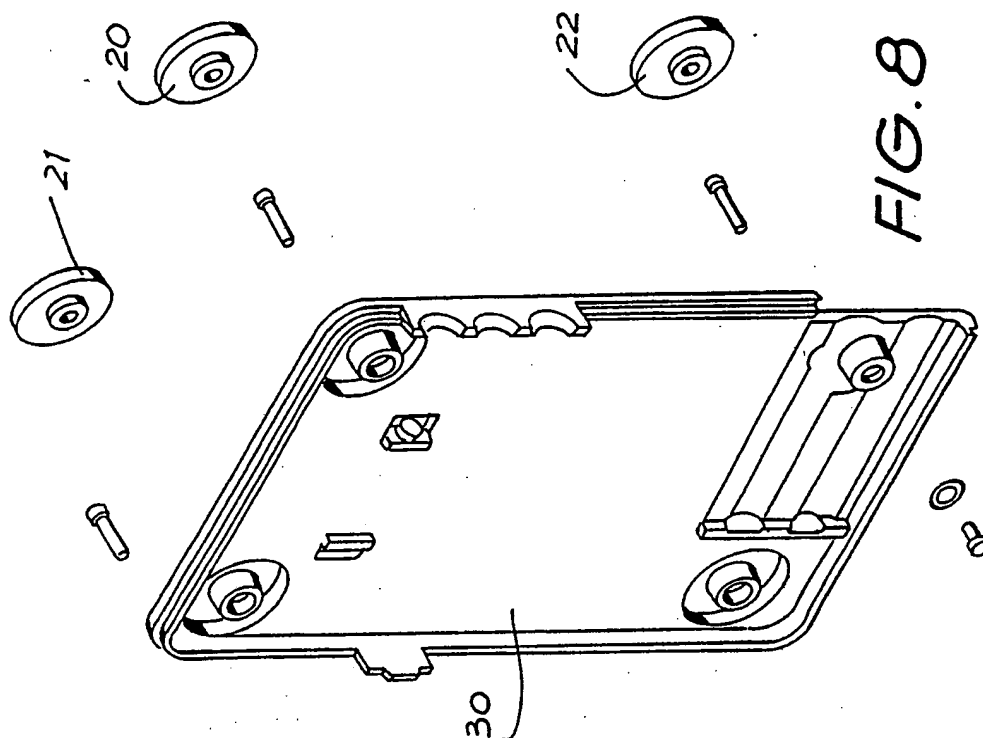


FIG. 8

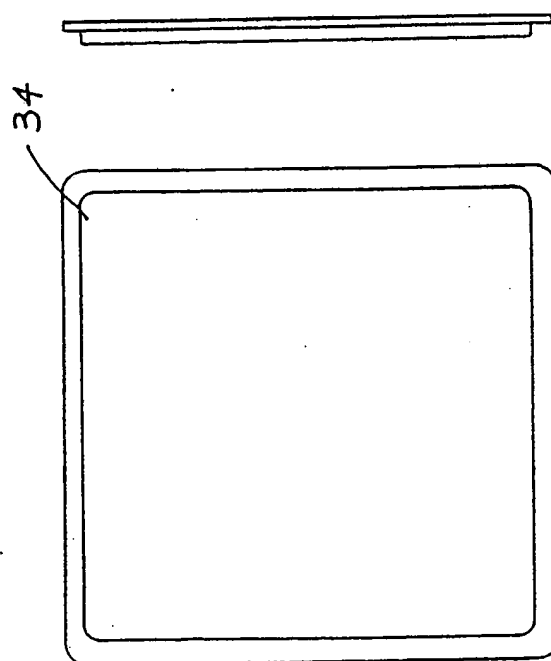


FIG. 7

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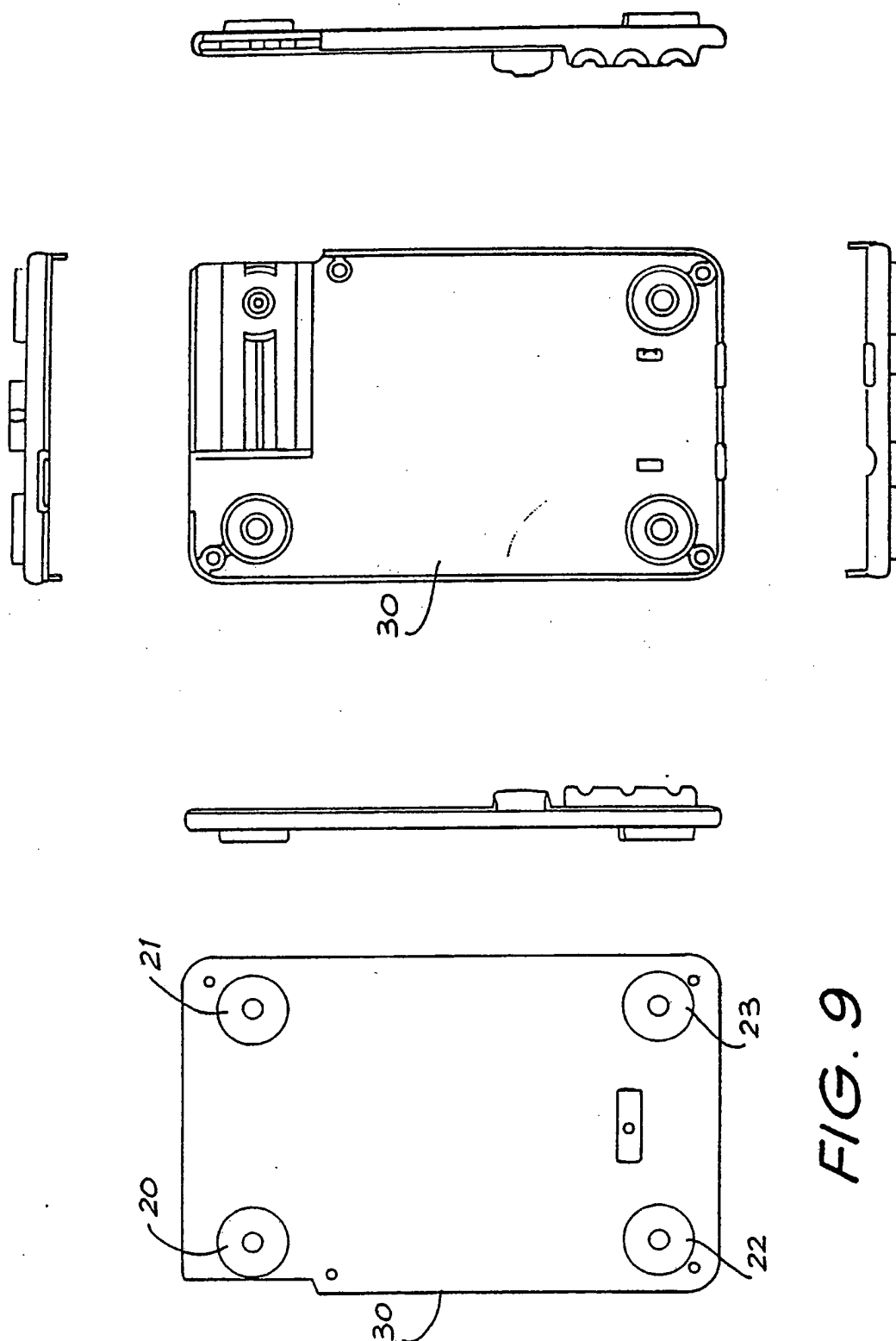


FIG. 9

SUBSTITUTE SHEET

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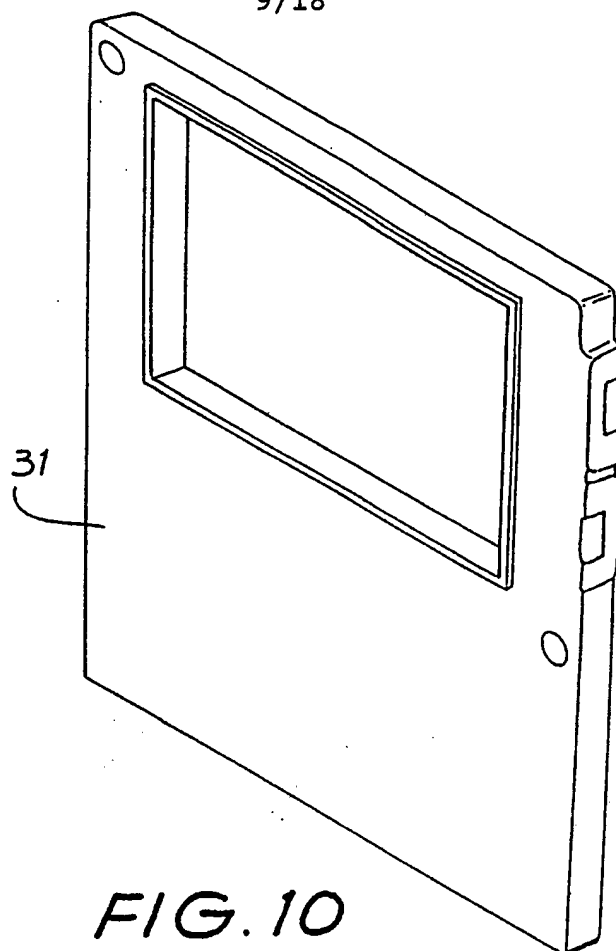


FIG. 10

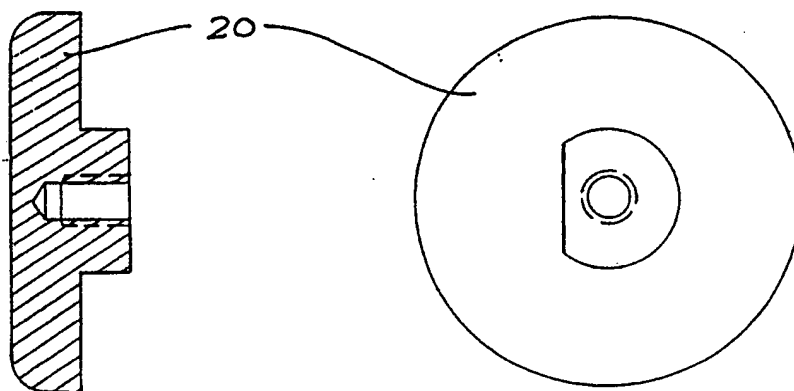
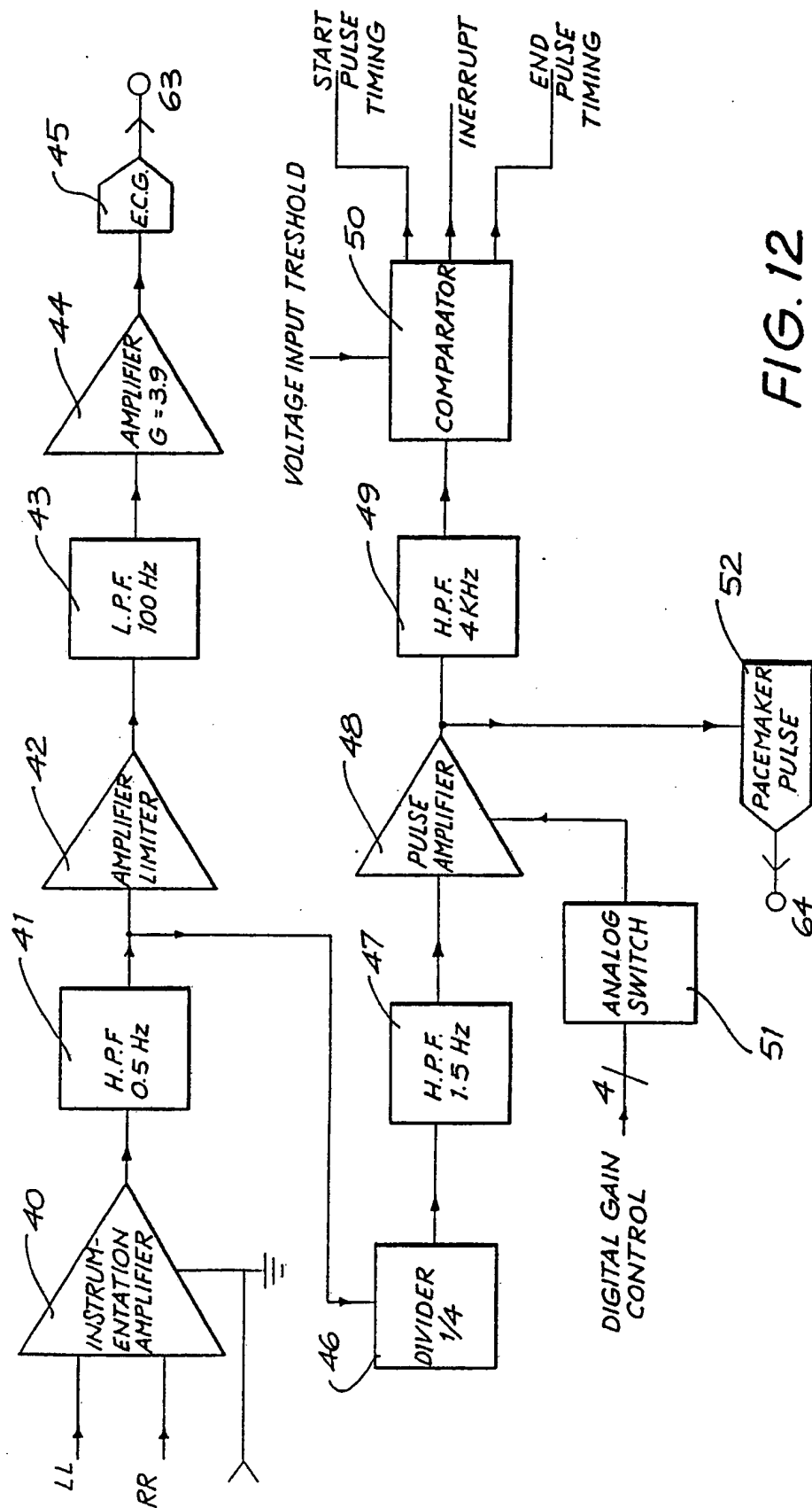


FIG. 11

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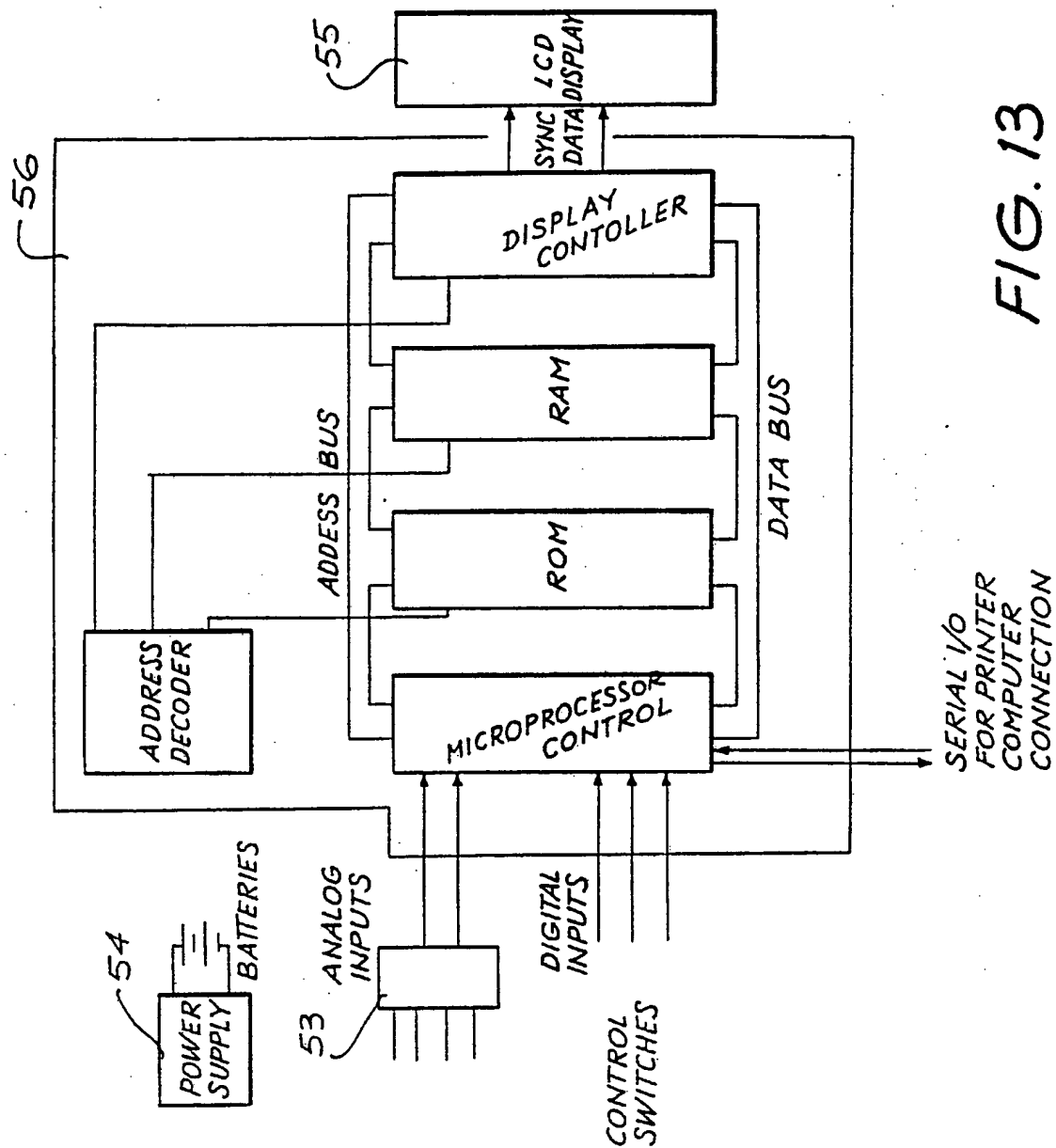


FIG. 13

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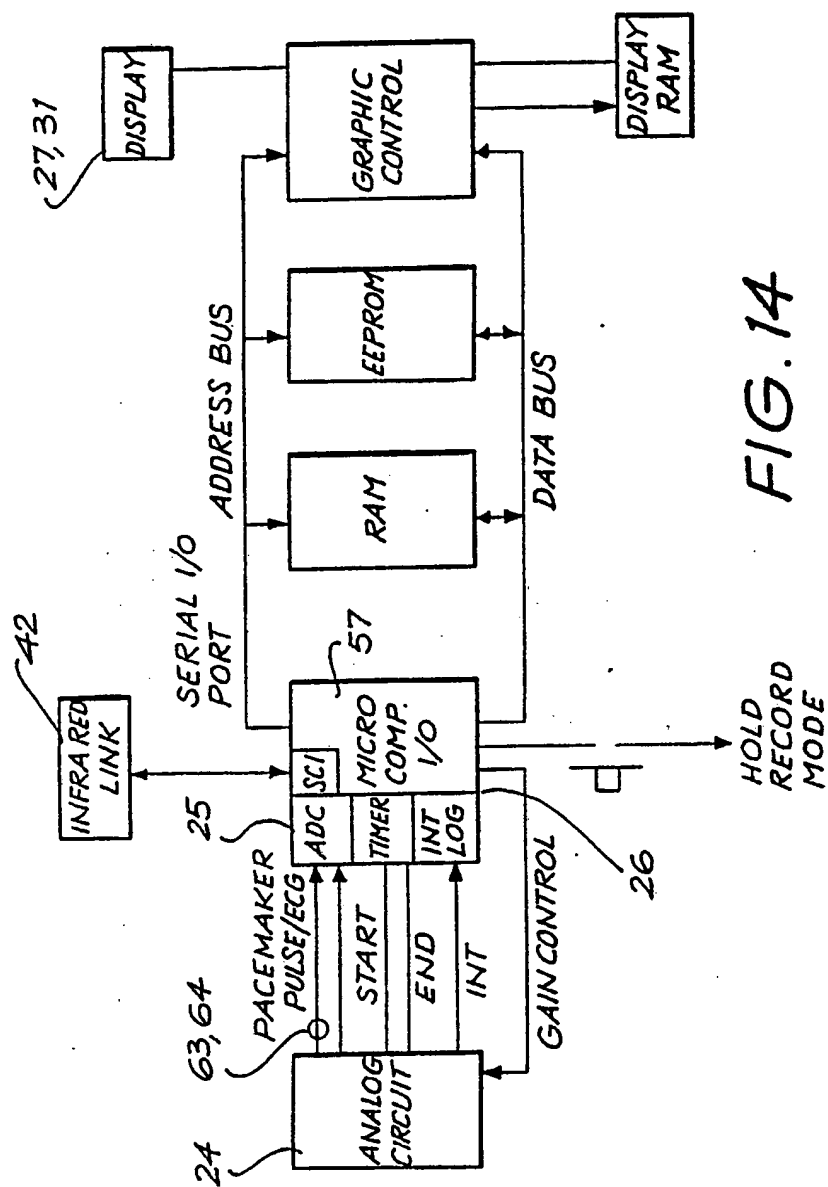
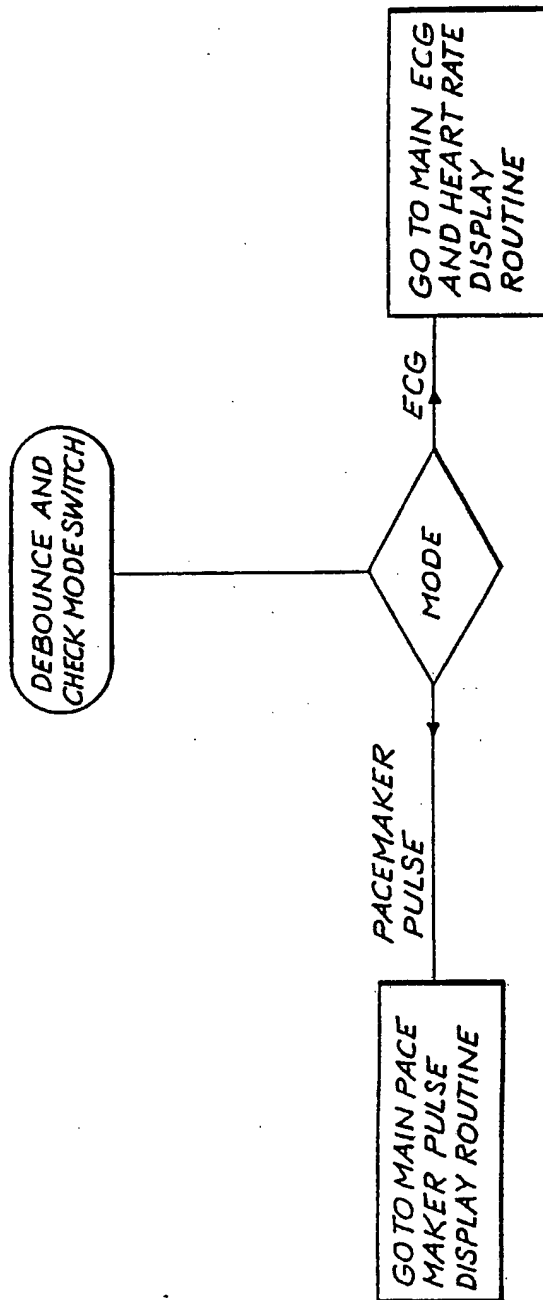


FIG. 14



MODE SWITCH INTERRUPT SERVICE ROUTINE

FIG. 15

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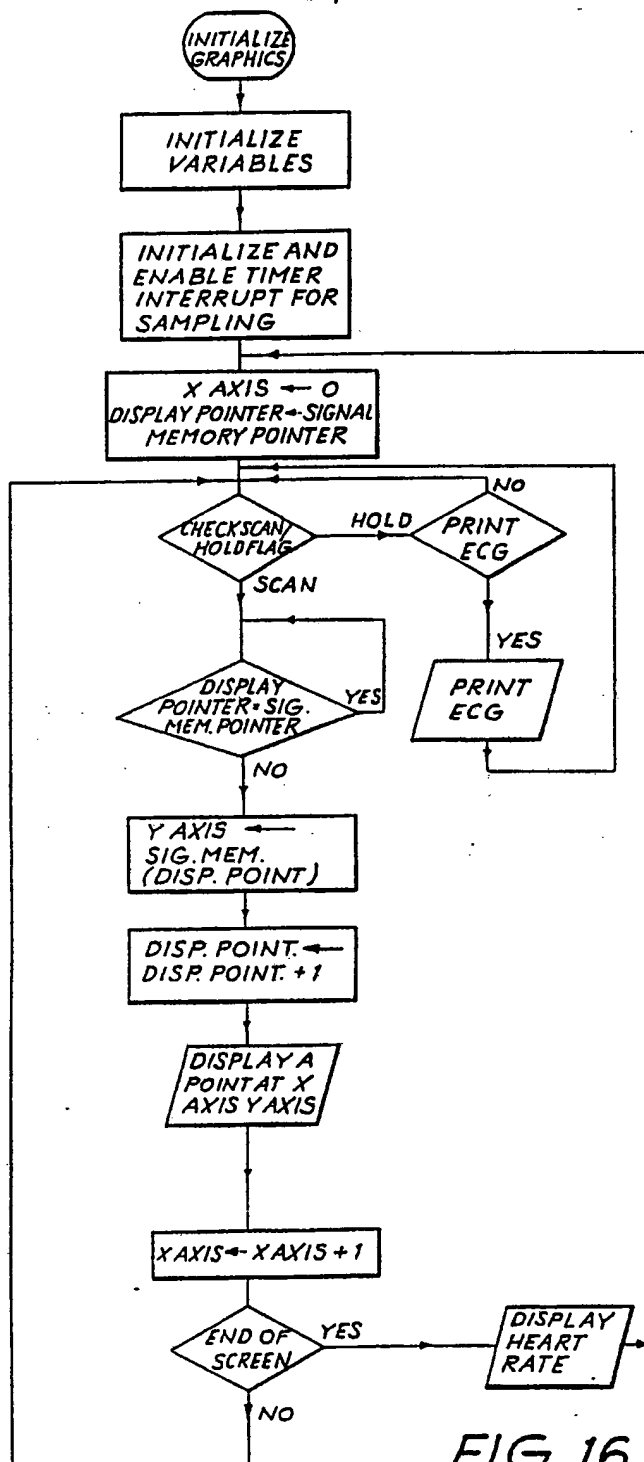
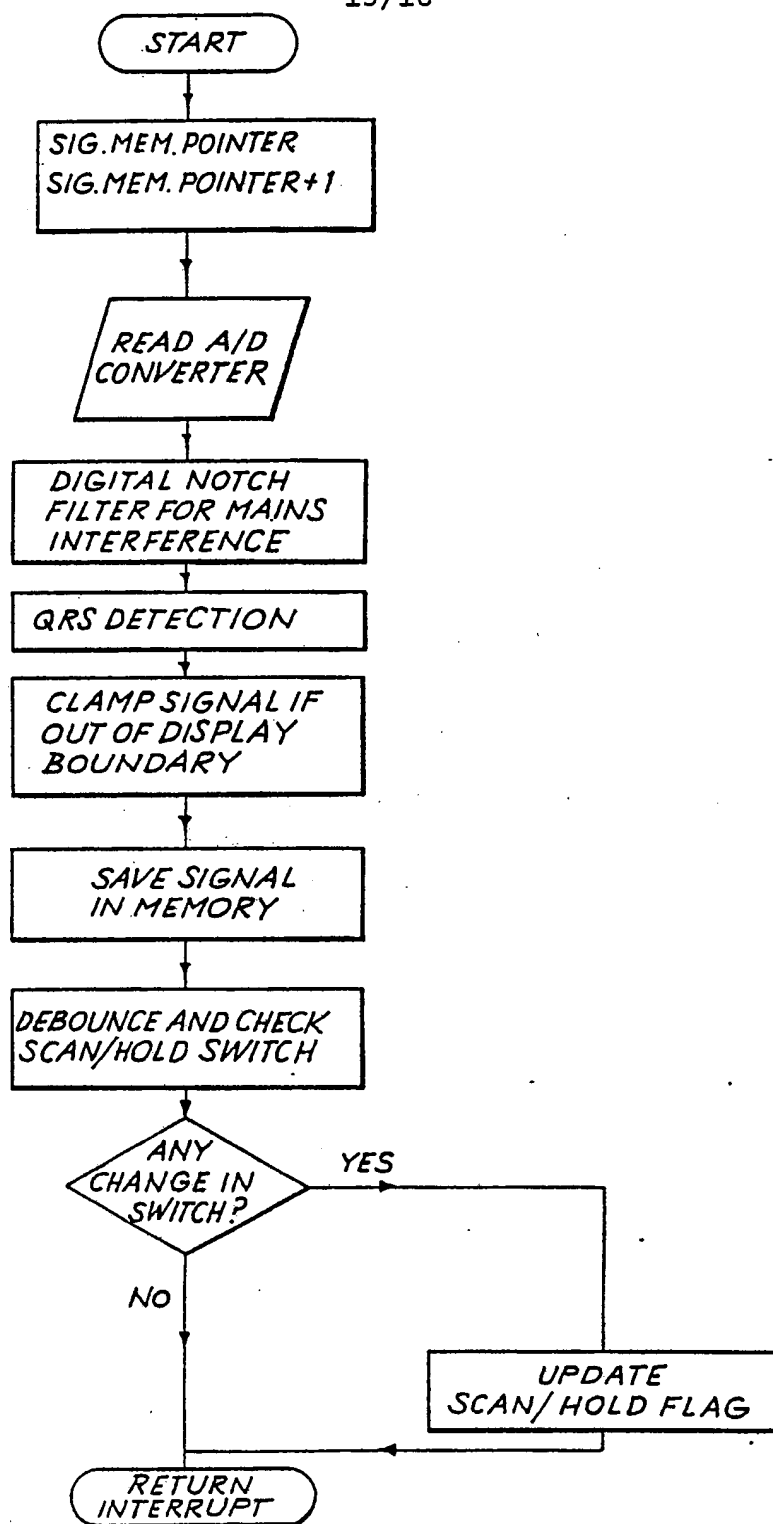


FIG. 16

MAIN ROUTINE FOR ECG AND HEART RATE DISPLAY

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**FIG. 17**

TIMER INTERRUPT SERVICE ROUTINE FOR
ECG AND HEART RATE DISPLAY

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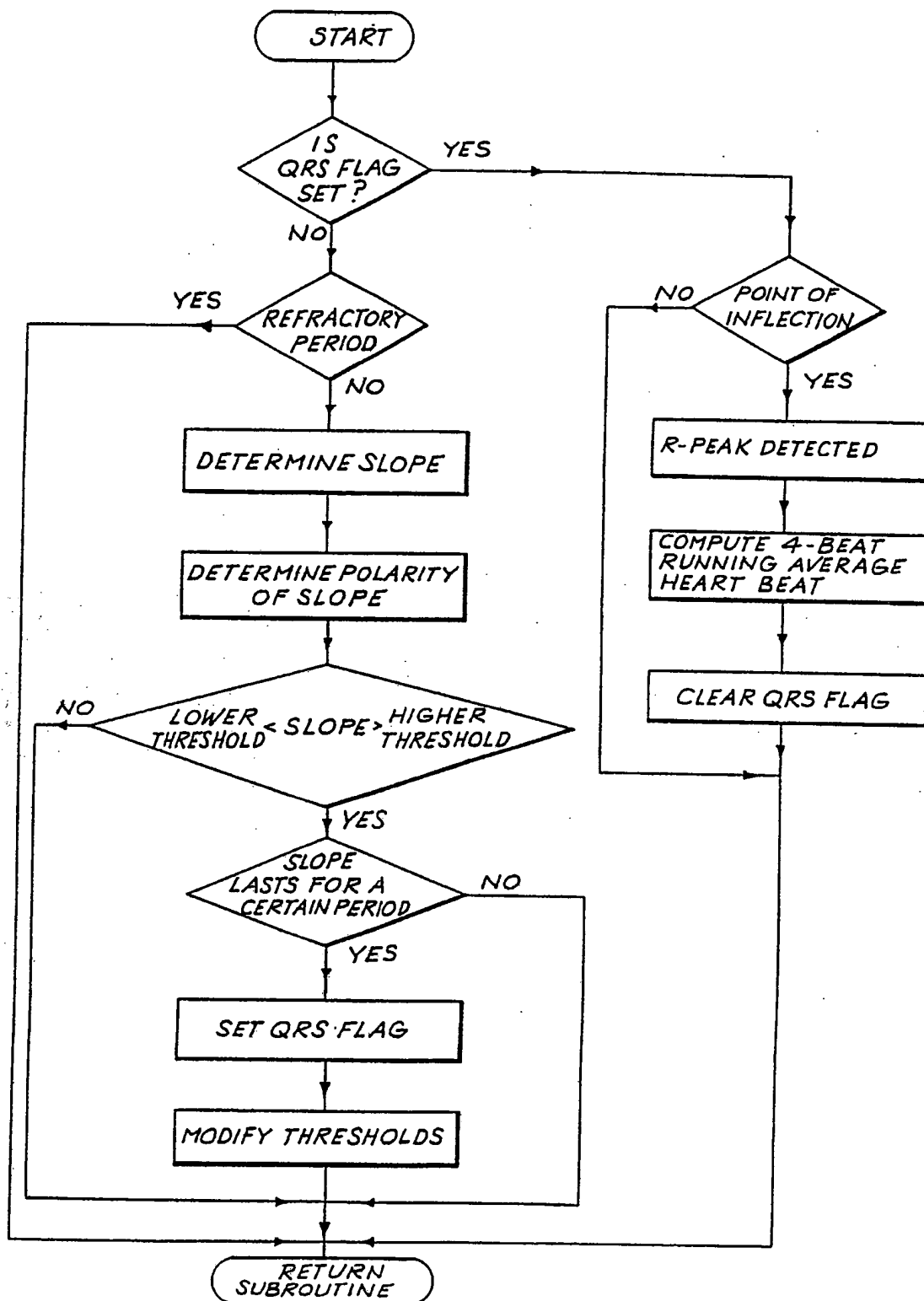


FIG. 18

QRS DETECTION ALGORITHM FOR
ECG AND HEART RATE DISPLAY.

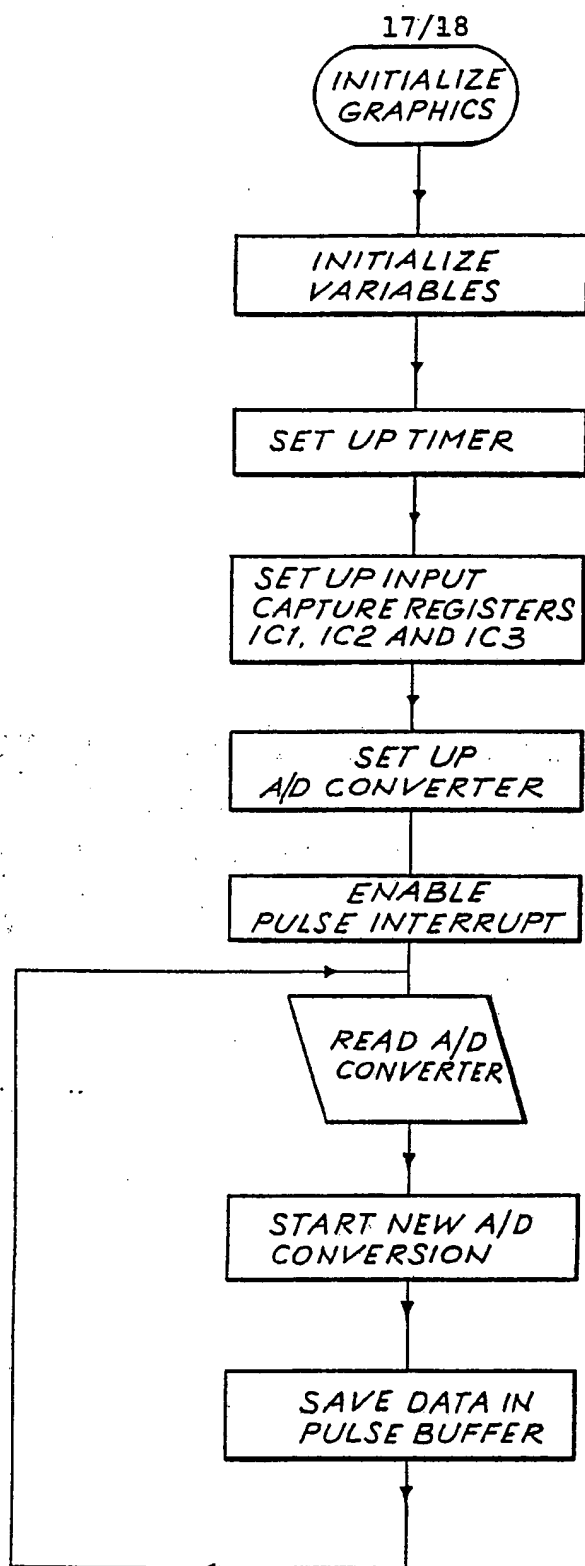
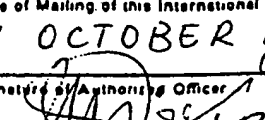


FIG. 19

MAIN ROUTINE FOR PACEMAKER PULSE DISPLAY ALGORITHM

INTERNATIONAL SEARCH REPORT

International Application No PCT/AU 88/00224

I. CLASSIFICATION OF SUBJECT MATTER : 1. Special Classification symbols apply, indicate all * According to International Patent Classification (IPC) or to both National Classification and IPC Int. Cl. ⁴ A61N 1/37; A61B 5/04		
II. FIELDS SEARCHED		
Minimum Documentation Searched *		
Classification System	Classification Symbols	
IPC	A61N 1/37, 1/36; A61B 5/04	
Documentation Searched other than Minimum Documentation to the extent that such Documents are included in the Fields Searched *		
AU : IPC as above		
III. DOCUMENTS CONSIDERED TO BE RELEVANT*		
Category *	Citation of Document, ** with indication, where appropriate, of the relevant passages **	Relevant to Claim No. **
X,Y	DE,A, 2216043 (FRITZ HELDIG & CO. GmbH) 4 October 1973 (04.10.73)	(1-10)
X,Y	DE,A, 3225223 (CORDIS CORP) 3 March 1983 (03.03.83)	(1-10)
Y	US,A, 4102346 (FULKER) 25 July 1978 (25.07.78)	(1-10)
Y	US,A, 4142533 (BROWNEE et al) 6 March 1979 (06.03.79)	(1-10)
A	US,A, 3759265 (THALER et al) 18 September 1973 (18.09.73)	-
A	US,A, 4509529 (MONEY et al) 9 April 1985 (09.04.85)	-
A	Derwent Abstract Accession no. 88-013556/02, Class P34, SU,A, 1316-685 (BEGOV) 15 June 1987 (15.06.87)	-
<div style="display: flex; justify-content: space-between;"> <div style="width: 48%;"> <p>* Special categories of cited documents: **</p> <p>"A" document defining the general state of the art which is not considered to be of particular relevance</p> <p>"E" earlier document but published on or after the international filing date</p> <p>"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)</p> <p>"O" document referring to an oral disclosure, use, exhibition or other means</p> <p>"P" document published prior to the international filing date but later than the priority date claimed</p> </div> <div style="width: 48%;"> <p>"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention</p> <p>"X" document of particular relevance: the claimed invention cannot be considered novel or cannot be considered to involve an inventive step</p> <p>"Y" document of particular relevance: the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.</p> <p>"Z" document member of the same patent family</p> </div> </div>		
IV. CERTIFICATION		
Date of the Actual Completion of the International Search 10 October 1988 (10.10.88)	Date of Mailing of this International Search Report 21 OCTOBER 1988 (21.10.88)	
International Searching Authority Australian Patent Office	Signed by the Authorizing Officer  E.N. PERRIS	

ANNEX TO THE INTERNATIONAL SEARCH REPORT ON

INTERNATIONAL APPLICATION NO. PCT/AU 88/00224

This Annex lists the known "A" publication level patent family members relating to the patent documents cited in the above-mentioned international search report. The Australian Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

Patent Document Cited in Search Report		Patent Family Members					
DE	3225223	FR	2512987	JP	58103469	US	4432360
US	4142533	US	4332256				
US	3759265	BE	730760	CA	927482	CH	494028
		DE	1916088	FR	2006030	GB	1266907
		IL	31473	NL	6905157	US	3528428
		US	3746005	US	3674015	BR	7204790
		DE	2216629	GB	1396365	NL	7207248
		US	3746006				
US	4509529	AU	13593/83	DE	3311509	FR	2529730
		GB	2123560				

END OF ANNEX